IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**No. 02 C 5129**
	)	
EASTERN SEAFOOD, INC. and MARIO FALCO,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

MATTHEW F. KENNELLY, District Judge:

Eastern Seafood, Inc. processes and distributes fish products. Mario Falco is Eastern's president and sole owner. In July 2002, the federal government sued Eastern and Falco, alleging that they were violating the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 331(k), by causing adulterated articles of food to be introduced into interstate commerce. In August 2002, the Court entered a consent decree of permanent injunction, which, among other things, permanently restrained and enjoined defendants "from doing or causing to be done, directly or indirectly, any act that violates 21 U.S.C. § 331(k) by causing food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) after shipment in interstate commerce." Consent Decree of Permanent Inj. § VIII. Now, nearly thirteen years later, defendants have moved to vacate the consent decree, arguing that its intent has been achieved and that its continued enforcement is unnecessary and oppressive. The government opposes the motion.

For the reasons set forth below, the Court denies defendants' motion to vacate. But given the decree's already long life, the Court is inclined to modify it to include a "sunset" provision allowing the court to terminate it if defendants are in continuous compliance for a period of three years. The Court orders the parties to show cause why such a modification would be inappropriate.

Background

In its complaint, filed in 2002, the government alleged that defendants had failed to develop and implement a Hazard Analysis and Critical Control Point (HACCP) plan for their fresh scombroid-forming fishery products (scombrotoxin fish products). According to the government, 21 C.F.R. § 123.6 required defendants to establish and implement a HACCP plan for their scombrotoxin fish products and to maintain a recordkeeping system to document the monitoring of critical control points for such products. Because defendants failed to establish and implement an HACCP plan and failed to maintain the proper recordkeeping system, the food they produced was adulterated within the meaning of 21 U.S.C. § 342(a)(4), and thus defendants violated 21 U.S.C. § 331(k) by causing their articles of food to become adulterated while held for sale after shipment in interstate commerce.

In August 2002, the Court entered the decree. Among other things, the decree:

- restrained and enjoined defendants from processing scombrotoxin fish products unless and until an independent HACCP expert prepared a HACCP plan that defendants implemented to the FDA's satisfaction;
- required defendants to implement a HACCP plan and maintain a HACCP control program for scombrotoxin once defendants' scombrotoxin fish products

operations resumed;

- permitted the FDA to make inspections of defendants' facilities without prior notice and when the FDA deems it necessary;
- required defendants to pay the costs of the FDA's inspections conducted pursuant to the decree; and
- restrained and enjoined defendants "from doing or causing to be done, directly or indirectly, any act that violates 21 U.S.C. § 331(k) by causing food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) after shipment in interstate commerce."

Decree § VIII. Under the decree, if the FDA determines that defendants have violated the decree, the Act, or FDA regulations, it may order cessation of defendants' operations or recall of defendants' products. Any decisions the FDA makes pursuant to the decree are considered final and reviewable by the Court only under an "arbitrary and capricious" standard.

The decree itself does not contain a "sunset" provision, but internal FDA guidelines provide, at least currently, that FDA may agree not to oppose a motion to vacate a consent decree injunction if the following conditions are met: (1) the agency has recent evidence that the defendant is in compliance with the Act, applicable regulations, and the decree; (2) the defendant has remained in "continuous compliance" for the "life of the sunset provision (virtually always five years)"; and (3) the defendant has provided FDA with an opportunity to consider whether to object to the motion. U.S. Food & Drug Admin., *Regulatory Procedures Manual* § 6-2-16 (2011), *available at* http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManua

l/UCM074317.pdf (last visited July 28, 2015). The government contends that none of these conditions has been met here. It objects to defendants' motion on the ground that defendants have not been in continuous compliance with the Act or the decree for the past five years.

Defendants contend that, during the decree's lifetime, they have been cooperative and compliant with the Act, FDA regulations, and the decree and that the FDA has not found contamination in any of their products and has not cited them with any official "violations" of the Act. As section IV of the decree required of defendants if they wanted to resume processing scombrotoxin fish products, they selected a HACCP expert who revised their HACCP plan, which the FDA ultimately approved and defendants implemented in 2002. Defendants note that in addition to implementing their upgraded HACCP plan, they have made upgrades to their processing facility and equipment to ensure compliance with the Act. These upgrades include: (1) hanging water hoses from the ceiling to prevent contact with food while not in use, (2) connecting waters sources to "backflow prevention devices" to prevent the formation of scombrotoxin bacteria, (3) using new digital temperature monitoring devices to ensure accurate monitoring, (4) upgrading the cooler containing shellfish and fresh fish to prevent spoilage and contamination, and (5) posting signs reminding employees to wear hair guards, aprons, and gloves in areas where necessary.

The government does not dispute defendants' contention that the FDA has discovered no actual contamination of defendants' fish products. The government denies, however, that defendants have remained in compliance with the Act. As evidence of defendants' noncompliance, the government provides examples, with

supporting signed declarations from FDA officials, of "significant" HACCP violations observed and documented by FDA investigators during inspections conducted in November–December 2009, March–April 2014, and April 2015. The FDA classified the 2009 and 2014 inspections as "Official Action Indicated" (OAI).[1] Though the government has not provided the inspection classification given for the 2015 inspection, the violations observed during that investigation were the same as or similar to those observed during the 2009 and 2014 investigations. In addition to classifying the inspections of Eastern as OAI, the FDA sent Falco a letter in 2010 informing him that Eastern was not in compliance with the Act, FDA regulations, or the decree and threatened issuing a shutdown notice, pursuant to the decree, if Eastern did not come into compliance.

Though not all of the cited violations involve the processing of scombrotoxin fish products, they do include defendants' failure to follow the procedures listed in their HACCP plans or to take the necessary steps to ensure that their HACCP plans were adequate to control food safety hazards. Defendants are thus alleged to be violating the same HACCP regulations, 21 C.F.R. § 123.6, that formed the basis for the

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[1] Following an FDA inspection, an establishment may receive one of three classifications respecting its compliance status. U.S. Food & Drug Admin. Transparency Task Force, *FDA Transparency Initiative* 27 (2010), *available at* http://www.fda.gov/downloads/AboutFDA/Transparency/PublicDisclosure/GlossaryofAcronymsandAbbreviations/UCM212110.pdf (last visited July 28, 2015). A classification of "No Action Indicated" (NAI) is given where the inspection revealed no objectionable conditions or practices or where no further actions would be justified. *Id.* A "Voluntary Action Indicated" (VAI) classification is given where the inspection reveals "more technical violations" or where objectionable practices or conditions do not meet the threshold of regulatory significance. *Id.* A classification of OAI is given where "significant objectionable conditions or practices [are] found and regulatory action is warranted . . . ." *Id.*

government's initial complaint in 2002.

In addition to the apparent noncompliance the FDA inspections revealed, the government also emphasizes what it characterizes as Falco's personal disregard for the decree's authority. The government cites, for example, to reports from FDA investigators stating that Falco told them on multiple occasions that the decree does not apply to him.

Discussion

Where, as here, a consent decree does not itself provide for the terms of its dissolution, parties seeking to modify or vacate the decree may do so pursuant to Federal Rule of Civil Procedure 60(b). *United States v. Krilich*, 303 F.3d 784, 789 (7th Cir. 2002). Though defendants do not specify the particular basis under Rule 60(b) on which they seek relief—indeed, they do not mention Rule 60(b)—the Court reads their petition as a request for relief under Rule 60(b)(5), which allows a court to modify or vacate a final judgment if "the judgment has been satisfied, released or discharged; it is based on an earlier judgment that has been reversed or vacated; or applying it prospectively is no longer equitable." Fed. R. Civ. P. 60(b)(5).[2] The party seeking to modify or vacate a consent decree pursuant to Rule 60(b)(5) "bears the burden of establishing that a significant change in circumstances warrants revision of the decree." *Rufo v. Inmates of Suffolk Cnty. Jail*, 502 U.S. 367, 383 (1992). The significant change may either be a change in "factual conditions or in law." *Id.*

[2] The only other ground for relief that might seem to apply, Rule 60(b)(6)'s catch-all provision, applies only where "extraordinary circumstances" justify modification. *Choice Hotels Int'l, Inc. v. Grover*, No. 14 C 3294, 2015 WL 4081169, at *1 (7th Cir. July 7, 2015). But defendants have not argued for relief on the basis of any extraordinary circumstances here.

In addition, the Supreme Court has held that, in the context of institutional reform litigation, a critical question in the Rule 60(b)(5) inquiry is whether the objective of the initial order has been achieved. *Home v. Flores*, 557 U.S. 433, 450 (2009) (reviewing denial of State of Arizona's request to modify decree declaring State to be in violation of federal education laws). "If a durable remedy has been implemented, continued enforcement of the order is not only unnecessary, but improper." *Id.*; *see also Bd. of Educ. of Oklahoma City Pub. Sch., Indep. Sch. Dist. No. 89, Oklahoma Cnty., Okl. v. Dowell*, 498 U.S. 237, 247 (1991) (holding, in desegregation litigation, that finding that school board was unlikely to "return to its former ways" would be finding that litigation's purposes had been fully achieved). Though *Horne* and *Dowell* involved federal decrees binding state and local governments and thus raised federalism concerns not present here, the general equitable principle they express seems applicable. Where a party can persuade a court that it has cured its initial violations and has taken steps to prevent future violations, it will no longer be equitable to continue to burden the party with a decree's continued prospective application.

Defendants' petition emphasizes the lack of "cited violations" during the decree's lifetime as well as defendants' "ongoing efforts to be compliant with the [Act and FDA regulations.]" Defs.' Reply at 7. Without any violations and without any attempts by the FDA to enforce the order in court, defendants argue, the intent of the order—defendants' implementation of a proper HACCP plan and the prevention of scombrotoxin contamination—has been achieved. Further, defendants say, if the Court vacates the decree, they still will be obligated to adhere to the Act and to FDA regulations and will be subject to periodic FDA inspections—albeit without having to pay

for them, as the decree requires. For these reasons, defendants contend, the continued operation of the decree serves no useful purpose and will only continue to burden defendants with the obligation to pay for FDA inspections that could or would occur even in the absence of the decree.

As discussed above, the Court agrees with defendants that it would be inequitable to continue to impose a decree whose primary effect is to shift investigation costs on a party that has taken steps to address the initial violation underlying the decree and has remained in compliance since the decree's entry. But that is not the case here, at least not at the present time. Rather, the government has provided evidence of defendants' recent noncompliance, and FDA has classified that noncompliance as OAI, a classification designating significant objectionable practices or conditions. Furthermore, the decree serves a purpose beyond cost shifting. Among other things, the purpose of the decree, given defendants' noncompliance with the Act prior to 2002, was to allow the FDA the opportunity to easily inspect defendants' establishment for evidence of additional noncompliance and to take swift action to protect the public health if needed. Thus until defendants are in full compliance, the decree's provisions—particularly those granting FDA the ability to cease defendants' operations or to recall food products—continue to serve a purpose by enabling the FDA to act quickly to protect the public from potentially adulterated food. Indeed, FDA believed it was necessary to threaten defendants with the possibility of issuing a shutdown notice pursuant to section IX of the decree as recently as January 2010.

Defendants imply that the noncompliance presented by the government is so insignificant that the Court should overlook it. For example, they cite the court's warning

in another case that "strict enforcement, by the F.D.A., of section 402 of the Act would result in the banning of literally all processed foods." *United States v. General Foods Corp*., 446 F. Supp. 740, 745 (N.D.N.Y.) *aff'd,* 591 F.2d 1332 (2d Cir. 1978). But the court in *General Foods* was referring specifically to the Act's provisions regarding levels of filth in food, under which a "violation is proven once the presence in the food of *any quantity of filth* is established." *Id.* at 744 (emphasis added). Thus any "expert armed with the proper equipment, could detect filth in virtually every food marketed." *Id.* at 745. The violations cited here—for example, failure to list adequate monitoring frequencies, verification procedures, or critical control points—are not the types of violations that likely would exist in the most compliant establishments.

Defendants have also listed, and have provided photographs to document, a number of updates they have made to their facilities, equipment, and policies. Had such updates resulted in defendants' continuous compliance with the Act, FDA regulations, and the decree, the Court might conclude that there has been a "significant change[s] in factual conditions," *Rufo*, 502 U.S at 383, or that defendants have implemented a "durable remedy," *Horne*, 557 U.S. at 450, thus warranting entry of an order vacating the decree. But FDA's discovery of apparent noncompliance as recently as April 2015 makes clear that any change in factual conditions or remedy implemented has not been "significant" or "durable" enough to allow the Court to do away with the decree at this time.[3]

[3] Falco's claimed statements suggesting disregard for the decree do not help defendants' argument that they have been cooperative and continually attempting to comply with the decree. But because the specific instances of noncompliance cited by the government are sufficient to require the Court to deny defendants' motion, Falco's

That said, it bears noting that the decree has been in existence for almost thirteen years. An express sunset provision ought to be added, to avoid question in the future over the circumstances under which the Court may vacate the decree. The Court also notes that the government has not advised the Court of any violations prior to 2009, suggesting that there may have been an extended period of compliance by defendants before the more recent episodes the government now cites. And none of the violations the government cites evidently was serious enough to cause the government to come back to court to seek relief under the decree. Given these circumstances, the Court is of the view that there should be a three-year sunset period, not the five-year period that the Court might have set had the issue come up at the time it entered the decree.

Conclusion

For the reasons stated above, the Court denies defendants' petition to vacate the consent decree [dkt. no. 3]. The Court proposes to modify the decree to allow for its dissolution upon a showing that defendants have been in continuous compliance with the decree, the Act, and applicable FDA regulations for three years. The parties are directed to show cause, by no later than August 14, 2015, why such a modification would be inappropriate. The case is set for a status hearing on August 26, 2015 at 9:30 a.m.

Date: July 31, 2015

MATTHEW F. KENNELLY
United States District Judge

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claimed negative attitude and beliefs about the decree do not factor into the Court's decision.